



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the National Mammography Quality Assurance Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organization interested in participating in the selection of nonvoting industry representatives to serve on the National Mammography Quality Assurance Advisory Committee (NMQAAC) in the Center for Devices and Radiological Health notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: All letters of interest and nominations should be submitted in writing to

Margaret J. Ames (see FOR FURTHER INFORMATION CONTACT).

FOR FURTHER INFORMATION CONTACT:

Margaret J. Ames,
Center for Devices and Radiological Health,
Food and Drug Administration,
10903 New Hampshire Ave.,
Bldg. 66, rm. 5234,
Silver Spring, MD 20993,
301-796-5960,
email: margaret.ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

The Mammography Quality Standards Reauthorization Act of 2004 (Public Law 108-365) requires the addition of at least two industry representatives with expertise in mammography equipment to the NMQAAC. The Agency is requesting nominations for nonvoting industry representatives on the NMQAAC.

I. NMQAAC

Advise FDA on: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and

health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

II. Qualifications

Persons nominated for membership as an industry representative on the NMQAAC must meet the following criteria: (1) Demonstrate expertise in mammography equipment and (2) be able to discuss equipment specifications and quality control procedures affecting mammography equipment. The industry representative must be able to represent the industry perspective on issues and actions before the advisory committee, serve as liaison between the committee and interested industry parties, and facilitate dialogue with the advisory committee on mammography equipment issues.

III. Selection Procedure

Any industry organization interested in participating in the selection of appropriate nonvoting members to represent industry interests should send a letter stating that interest to the FDA contact (see FOR FURTHER INFORMATION CONTACT) within 30 days of publication of this document (see DATES). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select candidates, within 60 days after the receipt of the FDA letter, to serve as nonvoting members to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting candidates. However, if no individual is selected within the 60 days, the

Commissioner of Food and Drugs will select the nonvoting members to represent industry interests.

IV. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see FOR FURTHER INFORMATION CONTACT) within 30 days of publication of this document (see DATES). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees and, therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the mammography manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 26, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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